

REMARKS

Claims 1, 3, 5-7, 10, 11, 13-18, 21-23, 25-31, 33, and 34-38 are currently pending in this application. By this amendment, Claims 3, 5, 6, 10, 11, 17, 23, 28, 31, and 33 have been canceled, Claims 1, 7, 13-16, 21, 22, 26, 27, 29, and 30 have been amended, and new Claims 39-44 have been added such that Claims 1, 7, 13-16, 18, 21, 22, 25-27, 29, 30, and 35-44 will be pending upon entry of the amendment. Support for the amendments and new claims is found in the specification and claims as filed.

Claim Rejections - 35 U.S.C. § 103(a) – Ditter in view of Karbachsch and Miller

Claims 1, 3, 5-7, 10, 11, 13-18, 21-23, 25-31, 33, and 34 have been rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,846,422 (hereinafter “Ditter”) in view of U.S. Patent No. 4,983,288 (hereinafter “Karbachs”) and U.S. Patent No. 4,906,371 (hereinafter “Miller”).

It is well settled that the Examiner “bears the initial burden of presenting a *prima facie* case of unpatentability...” *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007). Until the Examiner has established a *prima facie* case of obviousness, the Applicant need not present arguments or evidence of non-obviousness. To establish a *prima facie* case of obviousness, the Examiner must establish at least three elements. First, the prior art reference (or references when combined) must teach or suggest all of the claim limitations: “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 165 U.S.P.Q. 494, 496 (CCPA 1970); *see also M.P.E.P. § 2143.03*. Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091 (Fed. Cir. 1986); *see also M.P.E.P. § 2143.02*. And finally, the Examiner must articulate some reason to modify or combine the cited references that renders the claim obvious. Merely establishing that the claimed elements can be found in the prior art is not sufficient to establish a *prima facie* case of obviousness:

As is clear from cases such as *Adams*, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (emphasis added).

Instead, the Court has made clear that the Examiner must establish a reason one of skill in the art would have combined the elements of the prior art, and that such reason must be more than a conclusory statement that it would have been obvious.

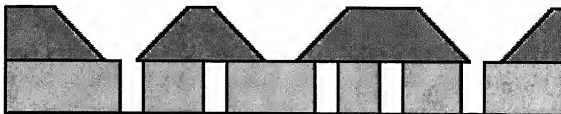
Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (C.A.Fed.2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”). *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-1741 (2007).

Applicants respectfully submit that the pending claims as amended are not obvious under 35 U.S.C. § 103(a) for the reasons detailed below.

Pending independent Claim 21 as amended, and from which the remaining pending claims depend, recites a filter laminate comprising “a plurality of discrete layers of material, wherein each layer is adjacent at least one other layer, said plurality of discrete layers comprising: a first membrane, wherein said first membrane is an asymmetric membrane having a skin surface and an open surface, wherein pores of the open surface are larger than pores of the skin surface, and wherein said asymmetric region comprises flow channels that gradually increase in diameter from said skin surface to said open surface; a second membrane, wherein said second membrane is an asymmetric membrane having a skin surface and an open surface, wherein pores of the open surface are larger than pores of the skin surface, and wherein said asymmetric region comprises flow channels that gradually increase in diameter from said skin surface to said open surface; and a bond between the skin surface of the first membrane and the skin surface of the second membrane, wherein the filter laminate has a higher bubble point than either the first membrane or the second membrane, wherein a bubble point of the filter laminate is greater than a bubble point of the first membrane layer and the second membrane layer in a skin-to-skin configuration without bonding, and wherein the filter laminate has a greater integrity than a combination wherein the skin surface of the first membrane and the skin surface of the second membrane are adjacent to each other but not bonded to each other, wherein the filter laminate has a flow rate

therethrough such that the filter laminate is configured for separation by filtration." As discussed in detail below, the combination of references cited does not teach or fairly suggest such a filter laminate as recited in Claim 21.

Karbachsich teaches a filter element comprising a prefiltering membrane and a final filtering membrane. The prefiltering membrane has an asymmetric configuration of pores, with the side of the membrane having larger pores on the upstream side of the filter path, and the side having smaller pores adjacent to the final filtering membrane. The final filtering membrane has "symmetrical pores where retention of particles occurs substantially exclusively at the surface. This markedly increases the useful life of the filter. The smaller particles traverse the first membrane and are separated from the fluid on the final filtering membrane. Because of the symmetrical structure of the latter, this membrane provides enhanced filtration reliability, preventing breakthrough of microorganisms, and therefore ensures sterile filtration." (see col. 2, line 68 through col. 3, line 7 of Karbachsch). Karbachsch further teaches that the prefiltering and final filtering membranes can be sealingly bonded together or can lie against one another. The configuration of Karbachsch can be depicted schematically as follows (see also Figs. 3, 4, and 5 of Karbachsch):



In contrast, the filter laminate of Claim 21 requires two asymmetric membranes, each having gradually increasing pore sizes from one side to another, to be bonded together between the sides of the membranes having smaller pores. Such a configuration as claimed in Claim 21 can be depicted schematically as follows (not to scale):



As discussed in the application as filed at page 10, ll. 11-21, a skin-to-skin bonded configuration for two asymmetric membranes, as recited in Claim 21, dramatically increases the bubble point of the resulting filter laminate above that of either of the single asymmetric layers,

due to the fact that the probability of lining up two large pores (which are responsible for the bubble point) is significantly reduced because most of the pores are "average" size, and probability greatly favors the situation where a large pore is confronted by numerous smaller pores. This results in greatly improved membrane integrity and, therefore, improved bacterial and particle retention. Simply placing two asymmetric membranes together, skin-to-skin, without bonding them, will not necessarily reduce the bubble point because the test air that flows through the top layer can travel laterally until it finds a larger pore in the bottom layer. Applicants also note that asymmetric membranes have higher permeabilities for a given bubble point compared to symmetric membranes. This offers advantages in that membrane capacity (the amount of liquid that can be filtered) is greater for the same surface area. Accordingly, the filter element of Karbachsch comprising, as the final filtering membrane, a symmetric membrane will be inferior to the filter laminate of Claim 21 comprising instead an asymmetric membrane (and having a minimum pore size the same as the pore size of the Karbachsch symmetric membrane) in terms of membrane capacity.

Karbachsch does not teach or suggest the filter laminate as in Claim 21, namely, two asymmetric membranes bonded together, much less a skin-to-skin bonded configuration or any advantage (e.g., superior bubble point) for a skin-to-skin configuration when bonded versus merely placing the skin sides of two asymmetric membranes adjacent to each other without bonding. Karbachsch instead teaches away from a configuration other than that disclosed (asymmetric prefiltration membrane and symmetric final filtering membrane) in that a symmetrical pore structure for the final filtering membrane is linked to the advantages of Karbachsch's filter element (enhanced filtration reliability, preventing breakthrough of microorganisms, sterile filtration).

Ditter and Miller include no teachings overcoming the deficiencies of Karbachsch. Ditter merely teaches an asymmetric membrane with a funnel-with-a neck structure (not to scale):



One of skill in the art might be motivated to substitute the asymmetric membrane of Ditter for the asymmetric membrane of Karbachsch, but would not be motivated to substitute it for the symmetric membrane and thus risk losing the advantages associated with the symmetric membrane. Applicants note that Ditter includes no teachings as to filter laminates. Miller discloses a filter element having a microporous filtration area bordered by substantially non-porous sealing areas of non-porous tape (see col. 12, ll. 55-59 of Miller) heat sealed to a microporous membrane (see col. 12, ll. 3-6). Accordingly, the filter element of Miller has two distinct types of regions: 1) porous filtration areas comprising layers that are adjacent to each other but not bonded to each other (non-laminated areas), through which filtration takes place; and 2) non-porous regions where layers are bonded to each other by a non-porous heat sealable tape (laminated areas), which results in a non-porous bond through which no filtration takes place. Miller discloses asymmetric membranes, but merely states that they are "membranes having one side formed with a very tight thin layer which is supported by a more porous open structure," but does not disclose any particular flow channel morphology, nor any specific configuration for two adjacent membrane layers. As such, Miller adds nothing overcoming the deficiencies of Karbachsch.

As discussed above, one of skill in the art would not be motivated to substitute an asymmetrical membrane for the symmetrical membrane of Karbachsch, because Karbachsch teaches that the advantages of the disclosed filter element are linked to the use of a symmetrical membrane. A *prima facie* case of obviousness cannot be established if the disclosure of the cited prior art, when taken as a whole, teaches away from the claimed invention. See, e.g., M.P.E.P. § 2141.02. Ditter merely teaches another type of asymmetric membrane, but nothing regarding filter laminates. Miller teaches a lamination method resulting in nonporous areas unsuitable for filtration adjacent to filtration areas where membranes are adjacent, but not bonded, to each other. Ditter and Miller therefore include no disclosure that overcomes the teaching away of Karbachsch.

Likewise, one of skill in the art would not be motivated to use a lamination method as in Miller (non-laminated filtration areas and laminated sealing areas) as it depends upon a nonlaminated (membranes not bonded) area for filtration; accordingly, the benefits as to bubble point set forth above for Applicants' claimed configuration will not be achieved. Likewise, the

use of two asymmetric membranes as in Applicants' filter laminate results in a higher membrane filtration capacity than a corresponding system employing an asymmetric membrane and a symmetric membrane. Superiority of a property shared with the prior art is evidence of nonobviousness. See M.P.E.P. § 716.02(a).

Accordingly, Applicants assert that the pending claims are not obvious over the combination of Ditter, Karbachsch, and Miller, and respectfully request that the rejection be withdrawn.

New Claims

New claims have been added directed to filter laminates having asymmetric membranes in a skin-to-open bonded orientation (Claims 39-41) and an open-to-open bonded orientation (Claims 42-44). As taught in the application as filed, the skin-to-open bonded configuration is particularly useful when two different pore sizes membranes are laminated together. When the open side of the more open membrane is generally oriented to be upstream, improved overall dirt holding capacity of the laminate is improved, and there is no downstream shedding when the skin side of the downstream membrane of the laminate is oriented downstream. The open-to-open bonded orientation of the laminate is useful as a quality assurance "postfilter" wherein the fluid to be filtered is already substantially free of particles. Since the flow path through such a laminate both begins and ends with a membrane skin, the open-to-open bonded laminate has a very high confidence of non-shedding. Neither of these configurations, much less their associated advantages, is taught or fairly suggested by the combination of Ditter, Karbachsch, and Miller. Accordingly, Applicants assert that the new claims are not obvious over the combination of Ditter, Karbachsch, and Miller.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior

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prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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